

## REMARKS

Claims 1-10, 23 and 25-31 are pending in this application. Claims 2-6 are withdrawn from consideration as being drawn to a non-elected invention or a non-elected species. Claims 1, 7-10, 23 and 25-31 are rejected. By the present amendment, claims 1, 2, 6, 23, 26, 27, 28 and 31 are hereby amended, and new claims 32 and 33 are hereby added. Applicant thanks the Examiner for the telephone conference of October 4, 2005, during which the amendment to claim 1 to recite circulating leukocytes and the techniques of flow cytometry were discussed.

Support for the amendment to claim 1 and new claim 33 to recite that levels of myeloperoxidase can be determined in circulating leukocytes as well as blood, plasma and serum, is found in original claim 6 and on page 9 of the specification. For clarity Claims 2 and 28 are hereby amended to recite the a peroxidase substrate is used in combination with flow cytometry procedures to determine myeloperoxidase activity or myeloperoxidase mass in one or more populations of the test subjects circulating leukocytes. Support for this amendment is found on pages 12 and 13 of the specification. Support for the amendment to claim 28 to recite that myeloperoxidase levels can be correlated with one or more flow cytometry parameters is found on pages 13 and 14 of the specification. Support for new claim 32 which recites that levels of myeloperoxidase can be determined using a combination of an antibody that binds to myeloperoxidase and flow cytometry is found on page 13 of the application and general knowledge in the art at the time the present application was filed about combining immunological methods with flow cytometry techniques to enhance the speed and ease with which levels of proteins in or on leukocytes are determined. (See attached article entitled "Flow Cytometric Quantitation of Immunofluorescence Intensity: Problems and Perspectives" indicating that, at least as early as 1998, flow cytometry in combination with antibodies was being used to determine levels of protein on or in cells.) Claim 31 is amended to be independent. As the amendment, and new claims are fully supported by the application as filed, the amendments and new claims add no new matter.

In view of the above-described amendments and following remarks, reconsideration of claims 1, 7-10, 23, and 25-31, and consideration of new claims 32 and 33 are respectfully requested.

§102 Rejections

Claims 1, 7, 9, 23, 26, and 27 are rejected under 35 USC §102(b) as being anticipated by Daugherty et al (Reference AN on the IDS submitted 8-12-02)(hereinafter Daugherty et al.)

Claims 1, 23, 26, and 27 have been amended to recite a method which comprises determining levels of MPO, MPO mass (and/or MPO activity) in blood, serum, plasma, or circulating leukocytes or any combination thereof from the test subject. Daugherty et al. does not disclose, teach or suggest determining levels of MPO in any of these bodily samples. Lacking such a disclosure, Daugherty et al. does not anticipate the methods of claims 1, 23, 26, and 27. Furthermore, Daugherty et al. does not anticipate the methods of claims 7 and 9, which depend from claim 1. Accordingly, applicants submit that the rejection should be withdrawn.

§112 Rejection.

Claims 1, 7-10, 23, 25-27 and 29-31 are rejected under 35 USC §112, first paragraph “because the specification, while being enabling for detecting increased MPO mass in certain myeloid cells, does not reasonably provide enablement for detecting increased MPO mass in any blood cell” (See paragraph 8 of the Office Action.)

As a point of clarification, claim 31, which has been amended to be independent, previously recited and continues to recite that the bodily sample is blood, serum, or plasma. Claim 31 has never recited that the sample is blood cells. Accordingly, applicants submit that the rejection of claim 31 should be withdrawn.

Claims 1, 23, 26, 27 and have been amended to replace the term “blood cells” with “circulating leukocytes”. In view of the amendment, applicants submit that claims 1, 23, 26, and 27, and the claims that depend therefrom, meet the enablement requirement of §112. Accordingly, applicants request that the rejection be withdrawn.

Claims 1, 7-10, 23, 25-27, and 29-31 are rejected under 35 USC §112, first paragraph, “as failing to comply with the written description requirement.” (See paragraph 9 of the Office Action.)

As a point of clarification, claim 31, which has been amended to be independent, which has been amended to be independent, previously recited and continues to recite that the bodily sample is blood, serum, or plasma. Claim 31 has never recited that the sample is blood cells.

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Accordingly, applicants submit that the rejection of claim 31 should be withdrawn.

Claims 1, 23, 26, 27 and have been amended to replace the term "blood cells" with "circulating leukocytes". In view of the amendment, applicants submit that claims 1, 23, 26, 27, and the claims that depend therefrom, meet the written description requirement of §112. Accordingly, applicants request that the rejection be withdrawn.

In view of the above-described amendments and remarks, applicants submit that claims 1-10, 23, and 25-31 and new claims 32 and 33 are now in conditions for allowance. Applicants request rejoinder of claims 2-6, and prompt notice of allowance of such allowance. If the Examiner has any questions regarding the amendments or remarks, he is encouraged to call the undersigned at the number listed below.

Date: November 30, 2005

Respectfully submitted,

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